Declaration

It is confirmed that following experimental procedures for forming implants in simulated vertebrae with a filler material alone and a filler material in a filling member have been performed under my supervision.

Example 1

A vertebra model purchased from Sawbones, a Divisional of Pacific Research Laboratories, Inc., USA, was used. A hole was drilled into the vertebral body and the drilling was stopped at 2-3 mm from anterior cortex. A filling member having a single fabric layer of meshed wall with a pore diameter of smaller than 0.1 mm was inserted into the vertebral body until the anterior end thereof reaches the proper position, which was 2-3 mm posterior to the anterior cortex. The filling member had a length of 30 mm.

A connection tube, which was provided with outer threads at one end engageable with inner threads of an injection port at the posterior end of the filling member, was fastened to the posterior end of the filling member. The connection tube was connected with a syringe at another end thereof. A bone filler material prepared from the following components (I), (II) and (III) was injected from the syringe into the filling member via the connection tube. The injected volume of PMMA was 3 ml.

Surgical Simplex^R P Radiopaque Bone Cement (Howmedica International, Ireland), which was packaged in two sterile components:

(I). One component is an ampoule containing 10 ml. of colourless liquid monomer that has a sweet slightly acid odour and has the following composition :

(a) Methyl methacrylate (monomer)	9.75 ml
(b) N,N-dimethyl para toluidine	0.25 ml
(c)Hydroquione, USP	0.75 mg

(II). The other component is a packet of 20g of finely divided powder of the following composition :

(a) Methyl methacrylate – styrene copolymer (contains 1.7% Benzoyl Peroxide)	15.0 g
(b) Polymethyl methacrylate	3.0 g
(c) Barium Sulphate E.P.	2.0 g

Osteo G from Central Medical Technology Co., Taiwan

(III). Osteo G is a packet of 5 g of finely divided powder of the following composition :

(a) Calcium sulfate hemihydrate	2.5 g
(b) Barium Sulfate	2.5 g

The bone filler material was prepared by mixing 5.0 ml of (I), 10.0 g of (II) and 4.0 g of (III) for two minutes, and the resulting mixture was filled in the syringe

immediately, which was then injected from the syringe at the third minute starting from the beginning of the mixing.

The connection tube was disconnected. A portion of the vertebral body was cut off 30 minutes after the connection tube being disconnected, and a photograph of the cut vertebra was taken.

Control 1

The vertebra model and the bone filler material used in this control were the same as in Example 1. A portion of the vertebral body was cut off to expose the cancellous bone. The cancellous bone was removed and the cut-off vertebral body was put back to joint with the cut vertebral body, so that a cavity was formed in the vertebral body. In order to prevent the filler material from leaking from the vertebra, a relatively viscous filler material prepared as follows and was injected into the vertebral body via a drilling hole formed thereon as taught in US patent No. 6,248,110 . The injected volume of PMMA was 3 ml.

The bone filler material was prepared by mixing 5.0 ml of (I), 10.0 g of (II) and 4.0 g of (III) for two minutes, and the resulting mixture was filled in the syringe immediately, which was then injected from the syringe at the sixth minute starting from the beginning of the mixing.

The cut-off portion of the vertebral body was removed 30 minutes after the injection, and a photograph of the cut vertebra was taken.

Results

In the attached photographs, the result of Example 1 is indicated by "Vessel-X (no cavity) This inventin", and the result of Control 1 is indicated by "a clump (in cavity) US-6248110). The attached photographs indicate the inventor's simulated experiment on the vertebra model, which was followed by the invention (Example 1) and the methodology of US patent No. 6,248,110 (Control 1). The results show that: the invention disclosed in US patent application serial number 10/611,998 could form a single complete clump according to the shape of the filling member without a cavity forming step in advance, and methodology of US patent No. 6,248,110 would form a stick shape of clump with a cavity forming step in advance.